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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,241	09/16/2003	Pal Maliga	RUT.97-0097US1-DIV	5658

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DANN, DORFMAN, HERRELL & SKILLMAN
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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,241

Applicant(s)

MALIGA ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/25/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group V (claims 5-7) in the reply filed on 18 August 2005 is acknowledged. The traversal is on the ground(s) that the Official Gazette Notice of November 19, 1996 and the MPEP 803.04 state that up to 10 sequences will be examined. This assertion is not convincing. These permit the examiner restrict to **up to ten** inventions and were intended to apply to short EST-like sequences with no known function. Since 1996, databases and resource allocations at the PTO have changed, and the examination of 10 sequences on the merits in the instant application would present a severe burden on PTO resources. Additionally, it is noted that one sequence is within the O.G. notice range of "up to ten" sequences. Accordingly, only the elected group has been examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4 are withdrawn from consideration as being drawn to non-elected inventions.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from pg 21, line 21, and pg 22, lines 6 and 20.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Objections

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3. Claims 6 and 7 are objected to because they start with an improper article.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A full review of the specification indicates that nucleic acids comprising NEP and PEP promoters are essential to the operation of the claimed invention. The level of skill and knowledge in the art at the time of filing was such that only a few of such promoters were identified; thus, there is no well-developed field of prior art.

The only species described by the specification are clpP promoters from several organisms. The prrn-114 promoter required by claims 6 and 7 is not described.

The specification describes a NEP promoter consensus that is present in some, but not all NEP promoters (pg 21-22). No PEP consensus is described. Thus, the necessary and sufficient structural elements of the claimed promoters are not described within the full scope of the claims.

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Hence, Applicant has not, in fact, described nucleic acids that comprise NEP and PEP promoters within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

6. Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain constructs comprising both NEP and PEP promoters, does not reasonably provide enablement for all constructs comprising both NEP and PEP promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any construct comprising both NEP and PEP promoters.

The instant specification, however, only provides guidance for analysis of plastid transcription in wildtype and *rpo*⁻ mutants, and the identification of NEP promoters from *clpP*, *rpoB*, *atpB* (example 1), and the PEP promoters from *clpP* (example 2-3); and promoter mapping in rice plastids (example 4).

The instant specification fails to provide guidance for NEP promoters from genes other than *clpP*, *rpoB* and *atpB*, and for PEP promoters from genes other than *clpP*. The specification also fails to teach the *Prrn-114* promoter required for the constructs of claims 6 and 7.

As the specification does not describe NEP and PEP promoters within the full scope of the claims, undue trial and error experimentation would be required to screen through the myriad

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of nucleic acids encompassed by the claims, to identify those that are NEP and PEP promoters, if such plants are even obtainable.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 5 is indefinite in its recitation of “transcription unit” because a transcription unit comprises operably linked promoters. It is unclear where the promoter(s) of the transcription unit are located relative to the promoters in part (b), especially since the part (b) promoters appear to be the ones regulating expression of the transcription unit.

Claim 5 is indefinite in its recitation of “A second PEP promoter” in part (b). It is not clear how there can be a second PEP promoter when there no first PEP promoter.

Claim 5 is indefinite in its recitation of “A DNA construct ... comprising ... expression of said transcription unit ...”. Expression is not a physical component of a construct, and should not be listed as such.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Maliga et al (US Patent 5,877,402, filed January 1994), taken with the evidence of Legen et al (2002, Plant J. 31:171-188).

The applied reference has a common [assignee OR inventor] with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Maliga et al teach constructs comprising the *rps16* promoter operably linked to the *uidA* coding region (Fig 22A and C). Legen et al teach that this promoter comprises NEP and PEP promoters (paragraph spanning the columns on pg 179).

11. Claims 6 and 7 are free of the prior art, given the failure of the prior art to teach or suggest a construct comprising a Prn-114 promoter and either a clpP-111 or clpP-53 promoter operably linked to a protein coding sequence.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The central fax number for official correspondence is (571) 273-8300.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
October 24, 2005



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER